

TCT-704

Short and Long Term Clinical Outcomes of Left Main Treatment with a Latest Generation Drug Eluting Stent

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Background: Information about the treatment approach for patients who suffer left main (LM) stenosis is limited and treatment option controversial. Aim: To analyze the short and long term outcomes of patients with LM disease treated with the latest generation drug eluting stent (DES) by pulling data from the NOBORI 2 and eNOBORI registries.

Methods: NOBORI 2 and eNOBORI are two large, prospective, single-arm, multicenter, registries that enrolled 3067 and 7750 patients respectively, out of which 62 and 212 had at least 1 lesion treated in the Left Main. All adverse events were adjudicated by an independent clinical event committee in NOBORI 2, while adjudication in eNOBORI (including stent thrombosis) is ongoing. The primary endpoint was Target Lesion Failure (TLF) defined as a composite of cardiac death (CD), target vessel related myocardial infarction (TV-MI) and target lesion revascularization (TLR).

Results: Patients were 72% male, 66±12y old, 34% had diabetes mellitus, 10% renal failure, 33% prior MI, 34% prior PCI and 25% previous cardiac surgery. In 19.5% of patients PCI was performed in the course of acute MI. Multiple vessels were treated in 55% of patients (2.5±1.6 lesions per patients). The lesions were complex (70% B2/C type), ostial (45%), calcified (46%), contained thrombus (8%) and 16% required bifurcation treatment. Pre- and post-dilatation were performed in 67% and 44% of lesions respectively. At 1-month, there were no deaths nor TLR, while there were 4 TV-MI (1.5%) and one TVR (0.5%). The TLF rate was 1.5%. In the cohort of patients followed at 3-year, 3 patients suffered a cardiac death (4.8%), 2 had an MI (3.2%), one patient underwent Re-PCI of LM (1.6%) and 6 patients (9.8%) of other vessels. TLF rate was 14.8%. A total of 93.3% of the patients were angina free. No stent thrombosis occurred up to 3 years.

Conclusions: Short and long term clinical outcomes of patients with LM disease treated with Nobori, DES with biodegradable polymer, are very encouraging. Low rate of adverse events and the absence of stent thrombosis up to 3 years in long term follow-up cohort suggest that this stent is valuable treatment option for patients with LM disease considered as candidates for PCI.

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A Comparison of Clinical Outcomes in Patients with Left Main Disease Treated with CABG vs Drug Eluting Stents. A Single Center Experience

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Background: Background: Coronary Artery Bypass Grafting is considered the first choice of treatment for unprotected left main disease (ULMD) compared to clinical treatment. Percutaneous treatment with drug eluting stents (DES) is showing to be a safe and effective alternative. The aim of this single center experience evaluation registry, is to compare MACE incidence between these two revascularization procedures: in hospital and late Stroke, myocardial infarction (MI) and target vessel revascularization (TVR).

Methods: Methods: from 11/2003 through 12/2010, 241 consecutive pts. with ULMD, underwent revascularization treatment being 114 with CABG and 127 with DES.

Results: Results: EuroScore ≥ 6 incidence was 32% in CABG group vs 49.5% in the DES group (p=0.005). Technique: CABG group with LIMA to LAD in 80.7%, bilateral mamary artery bypass 26.3%, 2.84 grafts/PT. DES group with 2.6 stents/PT., 92% with IVUS guidance. In-hospital outcomes CABG vs DES: Mortality 4.38% vs 1.57% (p=0.19), MI 0.87% vs 0.78% (p=0.93), TVR 0.87% vs 0.78% (p=0.93), Stroke 2.6% vs 0% (p=0.06), MACE 6.1% vs 1.57% (p=0.06). In CABG group mediastinitis incidence was 5.2% and reoperation need incidence of 7.8%. Acute and sub-acute in stent thrombosis in the DES group was 1.57%. Mean late follow up (940 days) showed (CABG vs DES): Mortality 12.8% vs 8% (p=0.22), TVR 10.1% vs 9.6% (p=0.89), MACE 19.2% vs 15.2% (p=0.41). In stent thrombosis 0.8%.

Conclusions: Conclusion: in this analysis, pts with ULMD treated with DES showed a trend toward to less incidence of stroke and MACE during in hospital phase compared to CABG, with late follow-up analysis showing equivalence.

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Dedicated Bifurcation Optimization Stent System BIOSS in Distal Left Main bifurcation stenosis – First-in-Human Results: Data from BIOSS Registry (Poland and Bulgaria)

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Background: The distal left main coronary artery disease is a particular form of coronary disease, still challenging for intervention. The results with regular drug-eluting stents (DES) are not optimal. The dedicated bifurcation stents are promising solution of this form of coronary disease.

Methods: Dedicated bifurcation paclitaxel-eluting stent BioSS® Expert and next generation sirolimus eluting stent BIOSS LIM (Balton, Poland) were used. This dedicated bifurcation device consists of two parts with different diameter, connected with two short bridges. BIOSS is mounted on dedicated bifurcation balloon – Bottle – with three markers (at both ends and at the mid part – for easy positioning at the level of the carina). 51 patients (17 from Bulgaria and 34 from Poland) were included and followed for 12 months into prospective, feasibility and safety assessment registry, with exclusions criteria STEMI, contraindication for 12 months DAP and lack of informed consent. The primary end-points of the study are: death, myocardial infarction, in-stent thrombosis and target lesion revascularization (in-hospital and 1, 3, 6, 12 months after the intervention). The first wave of registry started in Poland in 2009 and was followed in Bulgaria from second half of 2010.

Results: The average age of the enrolled patients (71% males) was 67±15 years. 80% had hypertension, and 44% have diabetes – 62% for the Bulgarian group and 30% for the Polish group. Most of patients enrolled have severe coronary disease – more than 50% had previous AMI, 60% had previous PCI, 13% were after CABG. All BioSS stents were implanted successfully without any periprocedural complication. Side branch stent was implanted more frequently in Polish group – 24% vs. 12% in Bulgarian Group. The TLR rate at 12 months was 11% - 5.9% (1/17 in BG) and 17.6 (6/34 in Poland); TVR rate was equivalent - 17.7% vs. 17.6% respectively. MACE rates differ: 23.5% in Bulgarian group (because of one possible stent thrombosis and MI during follow-up) and 17.6% (because of restenosis) in Polish group.

Conclusions: The BioSS bifurcation dedicated stent is a feasible device with promising safety and short-term clinical effectiveness/profile in LM bifurcation lesions.

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Drug-Eluting Stents for the Treatment of Left Main Coronary Artery Disease with Bifurcated Lesions: A Comparison with Sirolimus, Paclitaxel, Zotarolimus (Endeavor Resolute), BiolimusA9, EPC Capture and Everolimus-Eluting Stent: Multicenter Registry in Asia

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Background: The aim of this study is to compare the safety, efficacy and durability of Sirolimus (SES), Paclitaxel (PES), Zotarolimus (ZES-R/ Endeavor Resolute), BiolimusA9 (BES), EPC capture (ECS) and Everolimus-eluting stent (EES) on the outcome of patients with left main coronary arteries (LMT) stenosis.

Methods: A prospective analysis of 1127 LMT stenosis (321 SES, 277 PES, 129 ZES-R, 172 BES, 55 ECS, 173 EES) in six high volume Asian centers after successful stenting in LMT stenosis was performed. The study endpoints were 30 days major adverse cardiac events (MACE) and 12, 24, 36 and 48 months target lesion revascularization (TLR) and MACE in those 6 groups.

Results: See table for clinical results.

Conclusions: The use of drug-eluting stents in patients with LMT stenosis was safe with low acute complication. Patients treated with BES and EES showed lesser rate of restenosis compared with ZES-R and ECS.